OCT 2 6 2000

K 002316

510(k) Summary

Prepared by: Axon Systems, Inc.
400-2200 Oser Ave.
Hauppauge, NY 11788
Telephone: 631 436 5112
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Contact Person: Howard Bailin

Date Summary Prepared: July, 26, 2000

Name of Device: Phoenix Digital EEG

Common Name: Digital EEG

Classification: Electroencephalograph (per CFR 882.1400)

Predicate Devices: Nicolet Inc. Voyageur 510(k): K921927
Bio-logic Systems Corp Ceegraph 128-Channel Digital Recorder 510(k): K933233

Description of Device:

The Phoenix Digital EEG records and displays electrical activity of the brain (EEG). The system consists of a headbox/preamplifier, interface module, computer, monitor and keyboard and optional video camera, photic stimulator and printer. The system is available in both desktop and portable versions.

The Phoenix Digital EEG stores standard and user defined test protocols and montages and patient data for detailed review. Data can be reviewed in the time or frequency domain. Patient data may be exported to other software applications or printed. An intuitive user interface and the use of flexible screen definitions further enhances the users control of record review and allows fast access to key events in the clinical record.

The systems can be networked to share information. Patient records may be transferred from the Phoenix to any other compatible device on the network using the Ethernet, industry standard communication protocol.

High performance amplifiers and digital signal processing are used to insure high quality recorded data. A/D conversion is performed in the preamplifier/headbox to minimize interference and improve isolation.

Intended Use of the Device:

The Phoenix Digital EEG is intended for use in the recording and analysis of EEG tests. EEG testing is intended for use whenever it is necessary to measure and record the electrical activity of a patient's brain by attaching multiple electrodes on the scalp. The device can be used for routine testing or to provide continuous, long-term EEG and video monitoring.

The patient population includes adults, children and infants.

Summary of Technological Characteristics Compared to Predicate Devices:
The Phoenix Digital EEG acquires data in the same manner as the predicate devices. The Phoenix differs by adding additional analysis and display features. These additional features do not affect safety or efficacy.

Summary of Clinical Testing:
The Phoenix Digital EEG was tested and compared with predicate devices. See enclosed data. The results indicated no difference in the quality of data.

Summary of Non Clinical Testing:
Electrical safety and EMI Tests were performed in accordance with the requirements of IEC601.1 with no adverse findings. Tests using signal generators as stationary inputs confirm frequency response characteristics within specifications. Additional laboratory tests confirm the Phoenix Digital EEG meets or exceeds published specifications

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2000

Mr. Howard Bailin
Vice President
Axon Systems, Inc.
400-2200 Oser Avenue
Hauppauge, New York 11788

Re: K002316
Trade Name: Phoenix Digital EEG
Regulatory Class: II
Product Code: GWQ
Dated: June 26, 2000
Received: July 31, 2000

Dear Mr. Bailin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002316

Device Name: Phoenix Digital EEG

Indication for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002316

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The Counter Use _____

(Optional Format 1-2-96)